

## REMARKS

Claims 1-37 have been rejected and remain pending. In addition, claims 1, 7, 12, 20, 32, and 34 have been amended. Specifically, independent claims 1, 12, and 32 have been amended to indicate that the recited implantable medical device or non-woven framework comprises cells and is implantable within the vascular system of a mammal. Dependent claims 7, 20, and 34 have been amended to be consistent with amended independent claims 1, 12, and 32, respectively. Applicants' specification fully supports these claim amendments. For example, page 8, lines 6-8 disclose seeding medical devices with cells prior to implanting them into a patient. In addition, page 6, lines 1-30 disclose examples of implantable medical devices that are implantable into the vascular system of a mammal (e.g., vascular grafts and stents). Thus, no new matter has been added.

In light of these amendments and the following remarks, Applicants respectfully request reconsideration and allowance of claims 1-37.

### Rejections under 35 U.S.C. § 102(b)

The Examiner rejected claims 1-4, 12, 13, 24-26, and 31 under 35 U.S.C. § 102(b) as being anticipated by Ducheyne (U.S. Patent No. 5,030,233). Specifically, the Examiner stated that Ducheyne discloses "a porous metal material for surgical implantation made of metal fibers such as stainless steel or titanium" and "having a pore size of at least 150 micrometers." The Examiner also stated that the material of Ducheyne "is made by sintering the fibers together" and "is non-woven." In addition, the Examiner concluded that the "implant made from metal fibers disclosed by Ducheyne is the same as presently claimed."

Applicants respectfully disagree. To further prosecution, however, independent claims 1 and 12 have been amended to recite that the implantable medical device comprises cells and is implantable within the vascular system of a mammal. The Ducheyne reference fails to disclose such an implantable medical device. For example, at no point does the Ducheyne reference disclose an implantable device containing cells. Thus, independent claims 1 and 12, as amended, and dependent claims 3-4, 13, 24-26, and 31 are not anticipated.

In light of the above, Applicants respectfully request withdrawal of the rejections of claims 1-4, 12, 13, 24-26, and 31 under 35 U.S.C. § 102(b).

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claims 5-7, 14-20, and 32-34 under 35 U.S.C. § 103(a) as being unpatentable over Ducheyne (U.S. Patent No. 5,030,233) in view of Vacanti *et al.* (U.S. Patent No. 5,567,612). Specifically, the Examiner stated that the Vacanti *et al.* reference discloses an implant for generating tissue that can be made of polymer fibers, can be coated with extracellular matrix protein, and can contain cells. In addition, the Examiner alleged that it would have been obvious to provide the metal fiber implant of the Ducheyne reference with an extracellular matrix protein and/or cells for their expected function as disclosed by the Vacanti *et al.* reference. The Examiner also alleged that it would have been obvious to "use polymer fibers in place of metal fibers since it would have been apparent from Vacanti *et al.* that polymer fibers can provide the same type of function as the metal fibers when constructing an implant."

Applicants respectfully disagree. Claims 1, 12, and 32 have been amended to indicate that the recited implantable medical device or non-woven framework comprises cells and is implantable within the vascular system of a mammal. The Ducheyne reference discloses porous metal fiber mesh sheets for stabilizing prosthetic devices and repairing defective bone structures. As explained at column 4, lines 26-30, the "porous mesh material has pore sizes such that bony tissue can penetrate into the pores thereof when the porous mesh is pressed against living bone yet is capable of undergoing substantial bending and shaping without losing its structural integrity, including pore size distribution and volume density." The Vacanti *et al.* reference discloses using urothelial cells to create implants of urological structures such as the ureters, bladder, and urethra.

The cited references do not teach or suggest that a person having ordinary skill in the art should make or use the presently claimed implantable medical devices or non-woven frameworks. In fact, at no point does the combination of cited references teach or suggest that a person having ordinary skill in the art should make or use any device that contains cells and is implantable within the vascular system of a mammal. Moreover, contrary to the Examiner's assertion, a person having ordinary skill in the art reading the cited references would not have been motivated to provide the metal fiber implant of the Ducheyne reference with cells. This is especially true given the Ducheyne reference's teaching that the implanted material must meet certain criteria including, for example, stability for autoclaving. See, column 5, lines 20-25 and

column 5, lines 38-42. Applicants' respectfully submit that implantable medical devices comprises cells are not stable for autoclaving. Thus, a person having ordinary skill in the art appreciating the requirements set forth in the Ducheyne reference would not have been motivated to modify the materials of the Ducheyne reference as alleged by the Examiner. Taken together, the cited references do not render the present claims obvious.

In light of the above, Applicants respectfully request withdrawal of the rejections of claims 5-7, 14-20, and 32-34 under 35 U.S.C. § 103(a).

The Examiner also rejected claims 8, 21-23, and 35-37 under 35 U.S.C. § 103(a) as being unpatentable over Ducheyne (U.S. Patent No. 5,030,233) in view of Vacanti *et al.* (U.S. Patent No. 5,567,612) as applied to claims 5-7, 14-20, and 32-34 above, and further in view of Ferrara *et al.* (U.S. Patent No. 6,455,283). In addition, the Examiner rejected claims 9-11 and 27-30 under 35 U.S.C. § 103(a) as being unpatentable over Ducheyne (U.S. Patent No. 5,030,233) in view of Vacanti *et al.* (U.S. Patent No. 5,567,612) as applied to claims 5-7, 14-20, and 32-34 above, and further in view of Davidson (U.S. Patent No. 5,690,670).

Applicants respectfully disagree. Again, independent claims 1, 12, and 32 have been amended to indicate that the recited implantable medical device or non-woven framework comprises cells and is implantable within the vascular system of a mammal. As explained above, the combination of the Ducheyne and Vacanti *et al.* references fails to teach or suggest that a person having ordinary skill in the art should make or use the presently claimed implantable medical devices or non-woven frameworks. The Ferrara *et al.* and Davidson references do not cure the deficiencies of the Ducheyne and Vacanti *et al.* references. In fact, the Ferrara *et al.* reference discloses nucleic acids encoding vascular endothelial growth factor-E, while the Davidson reference discloses stents. At no point do the Ferrara *et al.* and Davidson references teach or suggest that a person having ordinary skill in the art should modify the materials of the Ducheyne reference as alleged by the Examiner. Thus, the cited references do not render the present claims obvious.

In light of the above, Applicants respectfully request withdrawal of the rejections of claims 8-11, 21-23, 27-30, and 35-37 under 35 U.S.C. § 103(a).

Applicant : Noel Caplice et al.  
Serial No. : 09/843,295  
Filed : April 25, 2001  
Page : 10 of 10

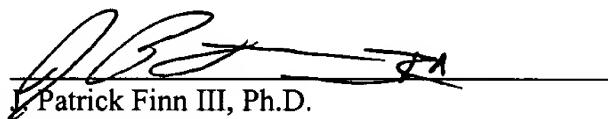
Attorney's Docket No.: 07039-175001

## CONCLUSION

Applicants submit that claims 1-37 are in condition for allowance, which action is requested. The Examiner is invited to call the undersigned agent at the telephone number below if such will advance prosecution of this application. Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: November 6, 2003



Patrick Finn III, Ph.D.  
Reg. No. 44,109

Fish & Richardson P.C., P.A.  
60 South Sixth Street  
Suite 3300  
Minneapolis, MN 55402  
Telephone: (612) 335-5070  
Facsimile: (612) 288-9696

60141222.doc